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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,420	06/27/2001	Charles D. Lennox	12013/51801	2674

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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,420

Applicant(s)

LENNOX, CHARLES D.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 06/27/01 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. The proper form for applicant to submit to the office is a PTO 1449. The references listed on the 892 is not proper since there is no place for the Examiner to sign and date and consider. Applicant is requested to resubmit the references in a proper format for the Examiner to consider.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1,3,7-9,12-14,16,20-25** are rejected under 35 U.S.C. 102(b) as being anticipated by levlev et al. (SU 1,069,826).

See figures 1-5. levlev et al. discloses a medical device (see figure 1) having a substrate (10) a coating (8) having a drug agent (/Pharmaceutical agent) incorporated therein and a sheath (7) having at least one perforation substantially closed when compressed and substantially open when expanded. (See figure 3 and 4). levlev et al.

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further teaches that the medical device can be an electroporation or an iontophoresis catheter. See page 2 . levlev et al. teaches the use of electrode with current-carrying conductor for introduction of pharmaceutical agents. (See page 1)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **5-6,18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over levlev et al. (SU 1,069,826) in view of Buelna et al. (U.S. Patent No. 5,653,689).

With respect to Figs. 1-5 of levlev et al., levlev et al. disclose the invention substantially as claimed. levlev et al. disclose perforations in the sheath (7) but does not disclose a perforation which is a longitudinal slit in shape. Buelna et al. teaches a sheath (135) having longitudinal slits which are arranged in a staggered formation in the same field of endeavor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the at least one perforation of levlev et al. with the longitudinal slit perforation of Buelna et al. as a mere substitution of parts performing the same function. Each element acting in the new environment as it did in the old is evidence of obviousness.

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Claims **2** and **15** are rejected under 35 U.S.C. 103(a) as being unpatentable over levlev et al. (SU 1,069,826) in view of Sahatjian et al. (U.S. Patent No.5,304,121).

With respect to Figs. 1-5 of levlev et al., levlev et al. discloses the invention substantially as claimed. levlev et al. discloses a polymer coating (8) on the substrate (10) however, levlev et al. is silent to the specific material of the coating. Sahatjian et al. teaches the substrate to be coated by dipping or spraying with a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, polyorthoesters, polylactic acids, polyglycolic acids, polycaprolactones, and polyacrylic acid in the same field of endeavor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the substrate of levlev et al. as taught by Sahatjian et al. in order to immobilize the pharmaceutical agents within.

Claims **4,10**, and **17** are rejected under 35 U.S.C. 103(a) as being unpatentable over levlev et al. (SU 1,069,826) in view of Williams et al. (U.S. Patent No.5964730).

With respect to Figs 1-5 of levlev et al. discloses the invention substantially as claimed. levlev et al. teaches a sheath however, levlev et al. is silent as to the materials of the sheath. Williams et al. teaches a sheath made of copolymers of ethylene and copolymers of ethylene vinyl in the analogous art of balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to construct the sheath of levlev et al. as taught by Williams et al. in order to make the sheath more easily formed over the substrate.

With respect to claim 10, levlev et al. shows the attachment of the sheath to the balloon catheter however, levlev et al. is silent to the type of attachment of the proximal and distal ends of the sheath to the balloon catheter. However, Williams et al. teaches securing of the balloon ends by means of adhesive and fusion welding or heat shrinking. See column 4, lines 43-48. It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the sheath of levlev et al. as taught by Williams et al. in order to secure the sheath to the balloon catheter.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over levlev et al. (SU 1,069,826) in view of Inoue (U.S. Patent No.5,100,386).

With respect to Figs 1-5 of levlev et al. discloses the invention substantially as claimed. levlev et al. show securement of the ends of the sheath/balloon However, levlev et al. is silent to the type of securement of the ends of the sheath/ balloon. Inoue teaches securement by filament of the balloon extreme ends. See figures 1,3. It would have been obvious to one of ordinary skill in the art to modify the securement of the sheath/ balloon ends with filament as taught by Inoue to provide further securement of the sheath/balloon in order to provide safety to the patient.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,280,411. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim a medical device comprising an expandable substrate, a coating and a sheath over said coating. The patent claims recite a medical device comprising an expandable substrate, a coating and an elastic sheath over the coating. Since a broad interpretation of sheath includes an elastic sheath, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,280,411 patent.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

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